IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NEUROSURGICAL CARE, LLC,

:

Plaintiff,

Case No. 2:19-cv-05751-JMY

V.

:

DOC SOLUTIONS LLC; and

MARK KAISER,

JURY DEMAND

Defendants.

JOINT REPORT OF RULE 26(f) MEETING

In accordance with Federal Rule of Civil Procedure 26(f), counsel for the parties conferred on January 21, 2020 and submit the following report of their meeting for the Court's consideration:

1. Discussion of Claims, Defenses, and Relevant Issues

Plaintiff's Statement

Plaintiff is an outpatient office providing medical services, founded by a practicing, board-certified neurosurgeon. Defendants fraudulently marketed Stivax to Plaintiff as Medicare reimbursable. As described in the Complaint, Plaintiff submitted 58 Stivax claims to Medicare for a total of \$396,973.58 relying on express written misrepresentations provided by Defendants. In December 2018, Plaintiff received a Civil Investigative Demand from the United States Attorney's Office for the Eastern District of Pennsylvania relating to its billing Medicare for Stivax based on the misrepresentations of Defendants. Distributors, such as Defendants, however continue to falsely market Stivax across the United States as Medicare reimbursable.

Stivax is manufactured by Biegler Gmbh, and was awarded FDA approval for marketing in the United States on May 26, 2016. Through its agent and consultant, Promedic, Inc., Biegler obtained FDA approval for Stivax as the substantial equivalent to the predicate device, the P-Stim System, also manufactured by Biegler. Just months before Biegler submitted its FDA application to market Stivax as P-Stim's replacement and substantial equivalent, on October 22, 2015, Medicare published guidance that the P-Stim System was not a Medicare-covered item or service, and therefore, not reimbursable by Medicare. Nonetheless, Biegler began manufacturing Stivax and importing it through Solace Advancement for distribution throughout the United States by distributors such as

Defendants, and doing so as Medicare reimbursable despite knowing Medicare clear directive from October 2015 as to P-Stim. This conduct is ongoing.

Discovery will focus on the breadth of the fraudulent scheme, Defendants' knowledge of it, and the relationships between Biegler, Promedic, Solace Advancement and the distribution network including Defendants. After filing the Amended Complaint on February 6, 2020, Plaintiff intends to file a motion for a preliminary injunction enjoining any further fraudulent marketing or representations that Stivax is Medicare reimbursable. If Defendants contend Stivax is Medicare reimbursable in response to the injunction motion, Plaintiff will request expedited discovery on the issues germane to the injunction motion. During the Rule 26(f) Conference, Plaintiff inquired as to whether Defendants would stipulate to the now indisputable fact that Stivax is not Medicare reimbursable, Defendants would not agree. Further, Defendants disclosed that they no longer sold Stivax during the Rule 26(f) Conference, Plaintiff inquired as to why Defendants exited the market and the circumstances as to that exit, but Defendants' counsel refused to respond stating instead that the Rule 26(f) Conference is not a discovery call. Across the nation, Stivax continues to be represented as Medicare reimbursable based on the fraudulent scheme executed by Defendants and others, the injunction sought by Plaintiff will eliminate that continued threat of harm, and as Plaintiff explained clearly during the Rule 26(f) Conference, we welcome a meet and confer about the scope of discovery and contested issues once Defendants have reviewed the motion for injunction.

Defendants' Statement

Defendants deny they previously engaged in fraudulent or negligent billing practices, as alleged by Plaintiff in Counts I-IV of the Complaint (Doc. No. 1).

Defendant Doc Solutions LLC ("Doc Solutions") is a now defunct medical device sales company that was based out of Bradenton, Florida, but last sold and shipped a Stivax device in the Spring of 2019. Doc Solutions was wound down by the Summer of 2019. Doc Solutions historically sold different medical devices to health care providers around the country, including a neurostimulator device called Stivax, which is manufactured by a European-based company called Biegler. Biegler previously contracted with a Michigan-based company, Solace Advancement ("Solace"), to distribute the Stivax device in the United States, and Solace, in turn, contracted with Doc Solutions, permitting Doc Solutions to sell the Stivax device to health care providers in the United States. As part of their business relationship with Doc Solutions, Solace provided advice and guidance to Doc Solutions regarding the design and use of the Stivax device. Solace likewise enlisted the assistance of Dr. Tim Warren to provide expert advice and guidance on appropriate coding regarding the Stivax device.

With the above backdrop in mind, this case arises out of a dispute between Doc Solutions and Plaintiff Neurosurgical Care LLC ("Neurosurgical"), a Pennsylvania-based provider of neurosurgical and related services. In the past, and as a result of its relationship with Solace, Doc Solutions sold Neurosurgical a number of Stivax devices. As it did, Doc Solutions offered training to Neurosurgical on how to use the devices.

Doc Solutions likewise directed Neurosurgical to coding recommendations previously prepared by Dr. Tim Warren, and, in doing so, Doc Solutions expressly relied upon Dr. Warren's expertise, as conveyed by Dr. Warren, Solace, and Solace's owner, Jim Carpenter. Thus, if billing codes used by Neurosurgical in connection with the Stivax device were later determined to be erroneous or improper, such incorrect or improper use was then unknown to Doc Solutions and Defendant Mark Kaiser, who both consistently relied upon the recommendations of Dr. Warren, Solace, and Mr. Carpenter.

Defendants anticipate that Plaintiff will file an Amended Complaint on or before February 6, and must answer or otherwise move in response in accordance with Rule 15(a). Defendants reserve the right to assert defenses, counterclaims, or third-party claims, as appropriate, and likewise reserve the opportunity to move to dismiss Plaintiff's claims. Defendants also anticipate filing a motion for summary judgment.

With respect to Plaintiff's stated intention to file a preliminary injunction motion against Defendants, counsel for Doc Solutions and Mark Kaiser have promptly informed Plaintiffs' counsel that there is no basis for such a motion as to Defendants Doc Solutions and Mark Kaiser. Specifically, Doc Solutions is no longer an operating business. Indeed, Doc Solutions last sold and shipped a Stivax device in the Spring of 2019, and Doc Solutions was wound down by the Summer of 2019. Furthermore, Mark Kaiser has ceased all work related to the health care industry, *i.e.*, he has not shut down Doc Solutions only to open up shop through another entity in an ongoing shell game.

We have offered to provide Plaintiff's counsel with additional support proving the truth of the above representations, should they desire it, in order to avoid unnecessary and costly litigation over this issue. If Plaintiffs proceed with their planned motion for preliminary injunction as to Defendants Doc Solutions and Mark Kaiser, this would be a tremendous waste of time, money, and resources for Plaintiffs, Defendants, and, most importantly, the Court. Indeed, such a motion would be incapable of remedying the non-existent conduct of Defendants.

2. Informal Disclosures

Defendants served their Initial Disclosures on January 16, 2020, in compliance with this Honorable Court's January 2, 2020, Order for Rule 16 Conference. Plaintiff served its Initial Disclosures on January 20, 2020. The parties have completed their Initial Disclosures pursuant to Rule 26(a)(1).

3. Formal Discovery

The parties have discussed pre-Rule 16 conference discovery.

Plaintiff will file an Amended Complaint on February 6, 2020, which will add parties, facts, and claims. As outlined above, Plaintiff will also file a motion for a preliminary injunction to stop any and all marketing of Stivax as Medicare reimbursable. If Defendants oppose that motion, Plaintiff will seek expedited discovery issues relevant to resolve that motion, including whether Stivax is reimbursable by Medicare.

Otherwise, the parties will exchange Interrogatories, Requests for Production of Documents and Requests for Admissions, if necessary. The parties may also serve subpoenas upon third-parties. Subsequently, depositions will be scheduled. Other than issues relevant to resolve Plaintiff's motion for preliminary injunction as set forth above, there is no need to conduct discovery in phases to prepare for the filing of dispositive motions or for settlement discussions at this time. Should the parties determine that limited discovery may aid in settlement negotiations once scheduling in this case is determined, they will alert the Court.

Consistent with the Court's standing practice, 120 days from the date of the Rule 16 pretrial conference is sufficient to conduct fact discovery.

The parties presently believe there will be limited electronic discovery in this matter and agree to exchange agreed upon protocols prior to any production.

The parties will discuss a protective order during the course of discovery related to potential issues arising from federal privacy laws governing health information, and other issues relating to business confidentiality concerns.

4. Expert Witness Disclosures

The parties have not yet determined whether or not expert witnesses will be needed. The proposed deadline for Rule 26(a)(2) expert disclosures is 30 days after the close of fact discovery, with rebuttal reports being due 15 days later, with expert depositions (if any) to be taken within 30 days following the submission of the expert's report. All reports, if any, are to be disclosed simultaneously by the parties at 5:00 p.m. ET on the due date.

5. Early Settlement or Resolution

The parties discussed alternative dispute resolution, and believe that an early settlement conference before a U.S. Magistrate Judge, to be scheduled as soon as possible at the Court's convenience, would be beneficial. If an early settlement conference is unsuccessful, subsequent alternative dispute resolution following discovery may be beneficial.

6. Magistrate Jurisdiction

The parties have discussed consenting to proceed before a United States Magistrate Judge. Outside the context of a settlement conference, as discussed above in section 5, the parties are unwilling to consent to proceed before a U.S. Magistrate Judge.

7. Trial Date

The parties agree that this case should be ready for trial 45 days after the Court's decision on dispositive motions, to be scheduled at His Honor's discretion. If the case cannot be resolved on cross motions for summary judgment, and is to be tried, the parties

respectfully request that a jury trial lasting eight trial days be scheduled before Your Honor, at a date set at Your Honor's discretion at least 45 days after decisions on cross motions for summary judgment.

8. Other Matters

N/A

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Dated: <u>January 24, 2020</u>

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Dated: <u>January 24, 2020</u>